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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,813	04/08/2004	Thomas A. Boyd	P0453.70112US01	9059

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
01/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,813	BOYD ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 11, 14-18, 21-32, 38, 39, 43, 45, 51-61, 64-70, 76, 77,82-85, 88, 95, 96, 103, 104, 107-109* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4-18,21-33,35,36,38-40,43,45,48-61,64-79,82-85,88,91-96,98,100-109 and 112-121.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4-10,12,13,33,35,36,40,48-50,71-75,78,79,91-94,98,100-102,105 and 106.

The previous indication of finality is withdrawn. In the rejection of record under 35 U.S.C. 103, the priority document for the reference of Levine, J.D., US 2004/0180916, does not recite the administration of methylnaltrexone.

Claims 2, 4-10, 12, 13, 33, 35, 36, 40, 48-50, 71-75, 78, 79, 91- 94, 98, 100-102, 105 and 106 remain withdrawn from consideration, and claims 1, 11, 14-18, 21-32, 38, 39, 43, 45, 51-61, 64-70, 76, 77, 82-85, 88, 95, 96, 103, 104, 107-109 and 112-121 are under consideration.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are reiterated or newly applied. They constitute the complete set presently applied to the instant application.

In the last Office Action claims 1, 11, 14-18, 21-32, 38, 39, 42, 43, 51, 56-61, 64-70, 76, 77, 113 and 115 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It was asserted Applicants have not conveyed possession of the invention with reasonable clarity to one skilled in the art because the disclosure lacks sufficient written description **for all claimed limitations**. Although it is agreed the specification teaches methylnaltrexone speeds up transit of material through the gut, sufficient guidance to support predictable operability of the invention to one of ordinary skill in the art with respect to all claimed limitations, such as treatment of the symptoms abdominal bloating, distension and stool consistency, as well as methods comprising administering an opioid agonist to a patient, for example, is absence.

The rejection of claims 11, 22-24, 27, 29, 31, 39, 61, 64, 65, 68, 77 and 113 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is maintained for the reasons of record.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 11, 14-18, 21-32, 38, 39, 43, 45, 51-61, 64-70, 76, 77, 82-85, 88, 95, 96, 103, 104, 107-109 and 112-121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 66 and 92 of copending Application No. 11/441452 because the copending application is drawn to pharmaceutical compositions comprising methylnaltrexone, optionally in combination with other therapeutic agents, as well as in the same dosages forms that are recited in the present claims, for use in the treatment of irritable bowel syndrome.

Claims 1, 11, 14-18, 21-32, 38, 39, 43, 45, 51-61, 64-70, 76, 77, 82-85, 88, 95, 96, 103, 104, 107-109 and 112-121 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims118-120 and 141-143 of copending Application No. 11/441,395. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending claims are drawn to the treatment of irritable bowel syndrome comprising administering methylnaltrexone.

These are a provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 11, 14-18, 21-32, 38, 39, 43, 45, 51-61, 64-70, 76, 77, 82-85, 88, 95, 96, 103, 104, 107-109 and 112-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minola et al., U.S. Patent 5,811,451.

Minola teaches the administration of methylnaltrexone along with calcium salts to treat irritable bowel syndrome (IBS). See column 3, lines 17 and 63-64. According to Minola, methylnaltrexone is among those opiate antagonists that may be administered to treat an endorphin-mediated pathology, such as IBS. See claims 1 and 2, columns 7-8. Minola states the choice of the opiate antagonist is within the purview of those skilled

in the art based on kinetics, potency, safety pharmacological risks, etc. See column 3, lines 47-50.

Claims 1, 11, 14-18, 21-32, 38, 39, 43, 45, 51-61, 64-70, 76, 77, 82-85, 88, 95, 96, 103, 104, 107-109 and 112-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al., S.S. Patent 6,734,188, in view of Drell et al., WO 99/22737.

Rhodes teaches the administration of an effective amount of any opioid antagonist to treat irritable bowel syndrome. See claims 15-17, column 8. Rhodes includes any pharmacologically acceptable derivative of opioid antagonists that exhibit the same type of pharmacological activity as those specifically exemplified in his teaching. Motivation to administer methylnaltrexone flows from Drell's teaching. See page 2, lines 21-25. Methylnaltrexone does not cross the blood brain barrier because it is a quaternary amine with a relatively higher polarity and reduced lipid solubility when compared to tertiary forms of opioid antagonists. Drell further teaches various dosage forms, as well as the addition administration of an opioid, in the Abstract. See page 6, lines 16-20, where dosages of methylnaltrexone are disclosed.

Therefore, in view of the combined teachings of Rhodes and Drell, one skilled in the art would have been motivated to administer methylnaltrexone to treat irritable bowel syndrome. Such would have been obvious because administering methylnaltrexone reduces the occurrence of side effects that occur following administration of centrally acting agents.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

January 9, 2009

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614